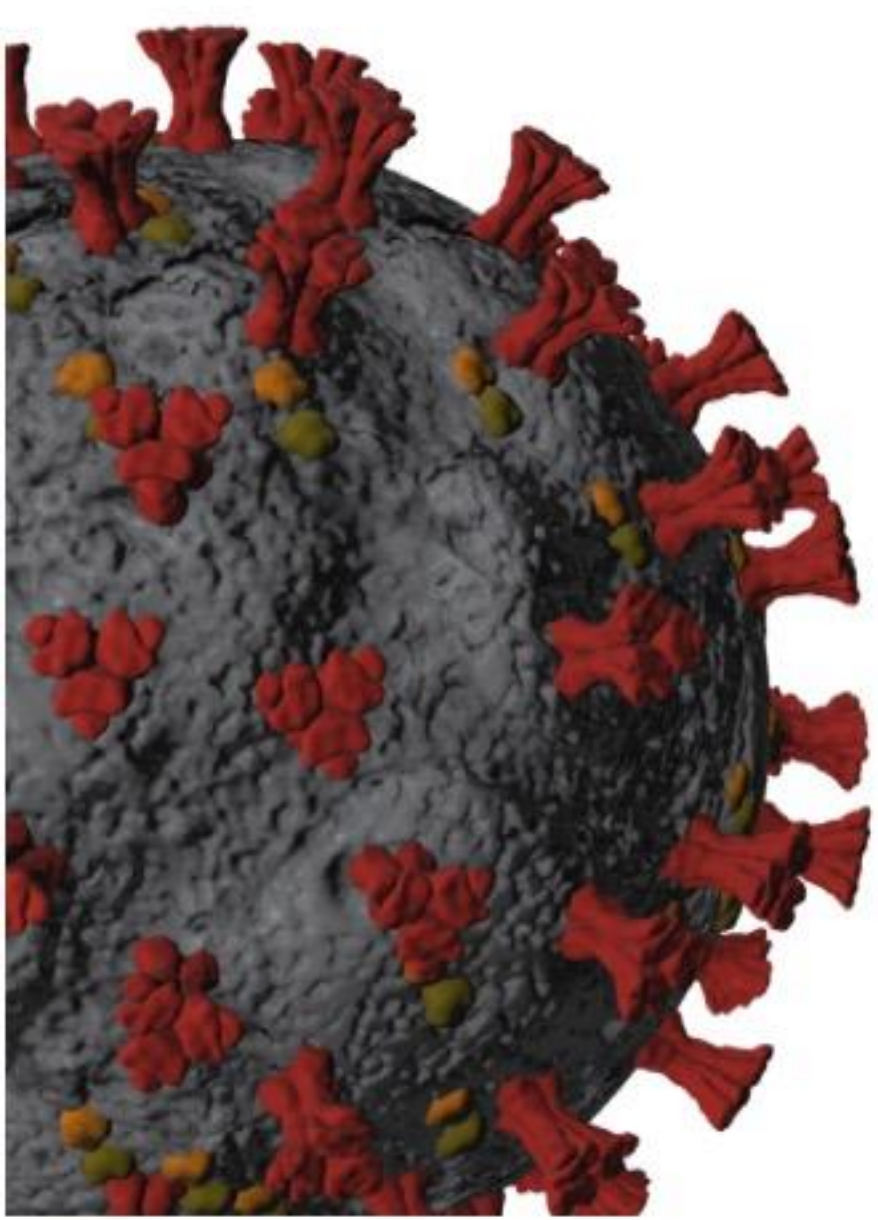


With
NATASHA CHIDA, MD, MSPH
MICHAEL MELIA, MD

JOHNS HOPKINS DIVISION OF INFECTIOUS DISEASES

COVID-19 GRAND ROUNDS

Does It Work—and—is It Safe?

Monitoring Safety & Efficacy of the Pfizer Vaccine Trials in the Midst of a Pandemic: The evolving role of the data safety monitoring committee

KATHRYN EDWARDS, MD
Professor of Pediatrics, Vanderbilt University Medical Center

WILLIAM GRUBER, MD
Senior Vice President of Vaccine Clinical Research & Development Pfizer, Inc.

JONATHAN ZENILMAN, MD
Professor of Medicine, Johns Hopkins Bayview Medical Center

4/25/2022

JOHNS HOPKINS MEDICINE

Session Outline

- By the end of this session, participants will be able to
  - Describe the development and implementation of the Pfizer COVID-19 vaccine program
  - Define the Role and Operations of Data Monitoring Committees (DMC)
  - Discuss how interim analyses contribute to safety in the Pfizer COVID-19 vaccine clinical trials

Disclosures

- Drs. Zenilman and Edwards are paid hourly consultants for their activities on the Pfizer C459 Vaccine Data Monitoring Committee (DMC)

- Dr. Gruber is a employee of Pfizer and receives salary , stock, and stock options from Pfizer Inc.

In April, 2020 Dr Gruber's team asked Jonathan , Kathy and 3 others (Larry Stanberry –Columbia, Steve Self (UW) and Bob Belshe (SLU) (later expanded with 2 more) to constitute the Data Safety Monitoring Committee for the Pfizer COVID Vaccine program.

This has been the ride of a lifetime….

COVID-19

These Secret Safety Panels Will Pick the COVID Vaccine Winners

By **Rachana Pradhan** • SEPTEMBER 24, 2020

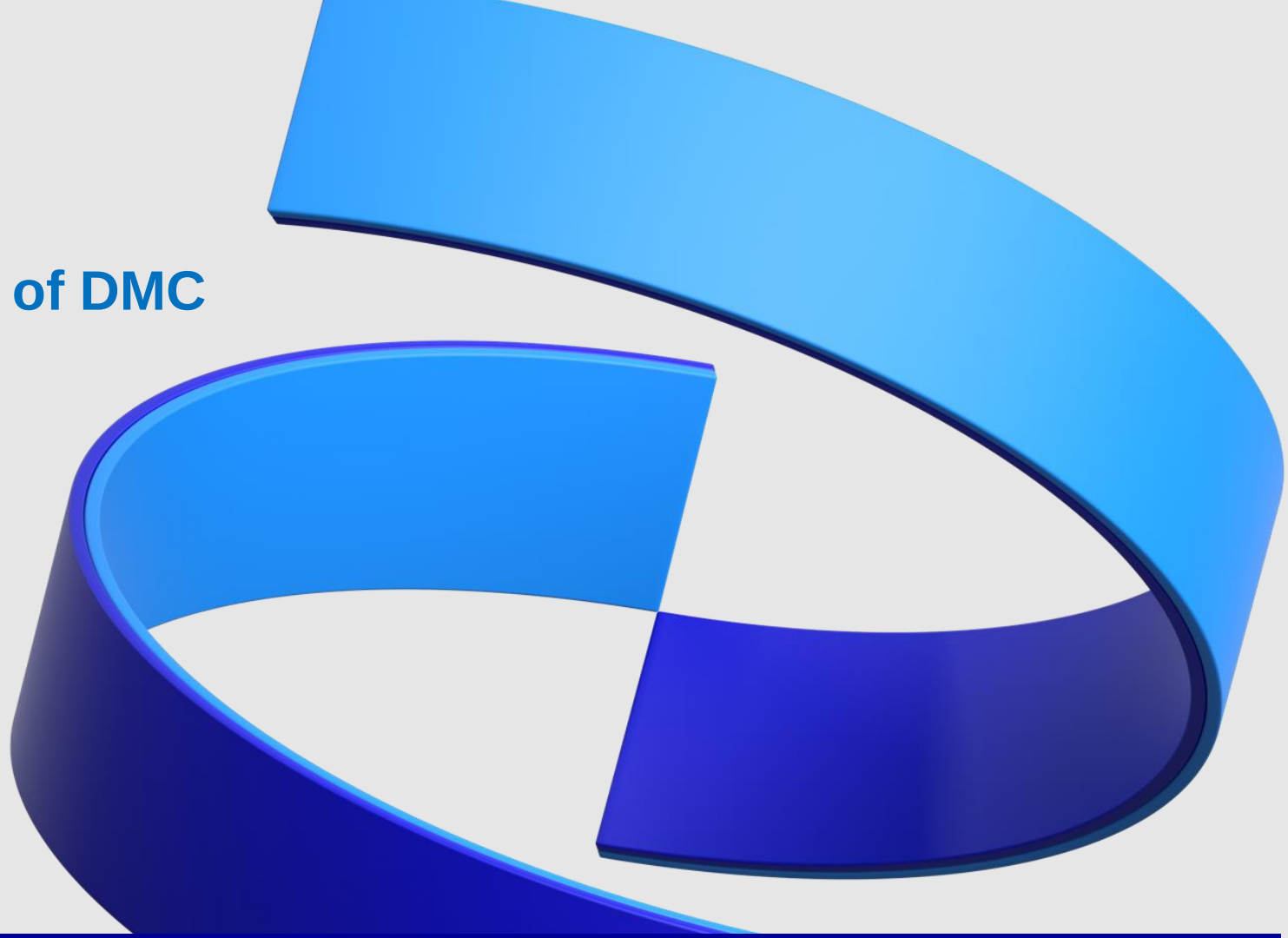
(Malte Mueller/Getty Images)

BNT162b2 Vaccine: Critical Role of DMC

Johns Hopkins Grand Rounds

Bill Gruber, MD, FAAP. FPIDS, FIDSA
SVP Vaccine Clinical Research and Development
Pfizer, Inc.

April 26, 2022



Indications and Recommendations:
https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/comirnaty-and-pfizer-biontech-covid-19-vaccine

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/index.html

FORWARD LOOKING STATEMENTS

This presentation contains forward-looking information about Pfizer's efforts to combat COVID-19, the collaboration between BioNTech and Pfizer to develop a COVID-19 vaccine, the BNT162b2 mRNA vaccine program, and the Pfizer-BioNTech COVID-19 Vaccine, also known as COMIRNATY (COVID-19 Vaccine, mRNA) (BNT162b2) (including qualitative assessments of available data, potential benefits, expectations for clinical trials, potential regulatory submissions, the anticipated timing of data readouts, regulatory submissions, regulatory approvals or authorizations and anticipated manufacturing, distribution and supply) involving substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as risks associated with preclinical and clinical data (including Phase 1/2/3 or Phase 4 data) for BNT162b2 or any other vaccine candidate in the BNT162 program in any of our studies in pediatrics, adolescents or adults or real world evidence, including the possibility of unfavorable new preclinical, clinical or safety data and further analyses of existing preclinical, clinical or safety data; the ability to produce comparable clinical or other results, including the rate of vaccine effectiveness and safety and tolerability profile observed to date, in additional analyses of the Phase 3 trial and additional studies, in real world data studies or in larger, more diverse populations following commercialization; the ability of BNT162b2 or any future vaccine to prevent COVID-19 caused by emerging virus variants; the risk that more widespread use of the vaccine will lead to new information about efficacy, safety, or other developments, including the risk of additional adverse reactions, some of which may be serious; the risk that preclinical and clinical trial data are subject to differing interpretations and assessments, including during the peer review/publication process, in the scientific community generally, and by regulatory authorities; whether and when additional data from the BNT162 mRNA vaccine program will be published in scientific journal publications and, if so, when and with what modifications and interpretations; whether regulatory authorities will be satisfied with the design of and results from these and any future preclinical and clinical studies; whether and when submissions to request emergency use or conditional marketing authorizations for BNT162b2 in additional populations, for a potential booster dose for BNT162b2 or any potential future vaccines (including potential future annual boosters or re-vaccinations) and/or other biologics license and/or emergency use authorization applications or amendments to any such applications may be filed in particular jurisdictions for BNT162b2 or any other potential vaccines that may arise from the BNT162 program, including a potential variant based, higher dose, or bivalent vaccine, and if obtained, whether or when such emergency use authorizations or licenses will expire or terminate; whether and when any applications that may be pending or filed for BNT162b2 (including any requested amendments to the emergency use or conditional marketing authorizations) or other vaccines that may result from the BNT162 program may be approved by particular regulatory authorities, which will depend on myriad factors, including making a determination as to whether the vaccine's benefits outweigh its known risks and determination of the vaccine's efficacy and, if approved, whether it will be commercially successful; decisions by regulatory authorities impacting labeling or marketing, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of a vaccine, including development of products or therapies by other companies; disruptions in the relationships between us and our collaboration partners, clinical trial sites or third-party suppliers; the risk that demand for any products may be reduced or no longer exist; risks related to the availability of raw materials to manufacture a vaccine; challenges related to our vaccine's formulation, dosing schedule and attendant storage, distribution and administration requirements, including risks related to storage and handling after delivery by Pfizer; the risk that we may not be able to successfully develop other vaccine formulations, booster doses or potential future annual boosters or re-vaccinations or new variant based vaccines; the risk that we may not be able to maintain or scale up manufacturing capacity on a timely basis or maintain access to logistics or supply channels commensurate with global demand for our vaccine, which would negatively impact our ability to supply the estimated numbers of doses of our vaccine within the projected time periods as previously indicated; whether and when additional supply agreements will be reached; uncertainties regarding the ability to obtain recommendations from vaccine advisory or technical committees and other public health authorities and uncertainties regarding the commercial impact of any such recommendations; challenges related to public vaccine confidence or awareness; uncertainties regarding the impact of COVID-19 on Pfizer's business, operations and financial results; and competitive developments. A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2021 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com. The forward-looking statements in this presentation speak only as of the original date of this presentation and we undertake no obligation to update or revise any of these statements.

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine

Fernando P. Polack, M.D., Stephen J. Thomas, M.D., Nicholas Kitchin, M.D., Judith Absalon, M.D., Alejandra Gurtman, M.D., Stephen Lockhart, D.M., John L. Perez, M.D., Gonzalo Pérez Marc, M.D., Edson D. Moreira, M.D., Cristiano Zerbini, M.D., Ruth Bailey, B.Sc., Kena A. Swanson, Ph.D., Satrajit Roychoudhury, Ph.D., Kenneth Koury, Ph.D., Ping Li, Ph.D., Warren V. Kalina, Ph.D., David Cooper, Ph.D., Robert W. Frenck, Jr., M.D., Laura L. Hammitt, M.D., Özlem Türeci, M.D., Haylene Nell, M.D., Axel Schaefer, M.D., Serhat Ünal, M.D., Dina B. Tresnan, D.V.M., Ph.D., Susan Mather, M.D., Philip R. Dormitzer, M.D., Ph.D., Uğur Şahin, M.D., Kathrin U. Jansen, Ph.D., and William C. Gruber, M.D., for the C4591001 Clinical Trial Group*

This article was published on December 10, 2020, at NEJM.org.

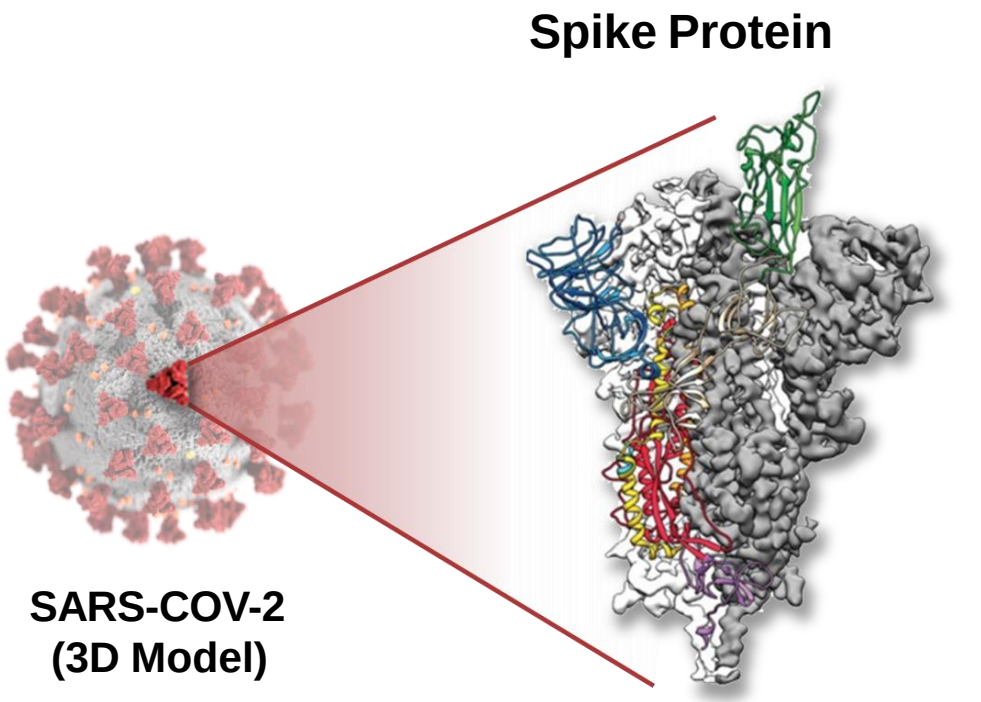
Data Monitoring Committee, Interim Analysis
Nov 8, 2021

Jonathan Zenilman, MD (Chair)
Kathryn Edwards, MD
Robert Belshe, MD
Lawrence Stanberry, MD, Ph.D.
Steve Self, PhD

Pfizer Unblinded Team
Shon Remich, MD
Satrajit Roychoudhury, Ph.D.

DMC now also includes Robert Philips Heine, MD, Heather S Lipkind, MD

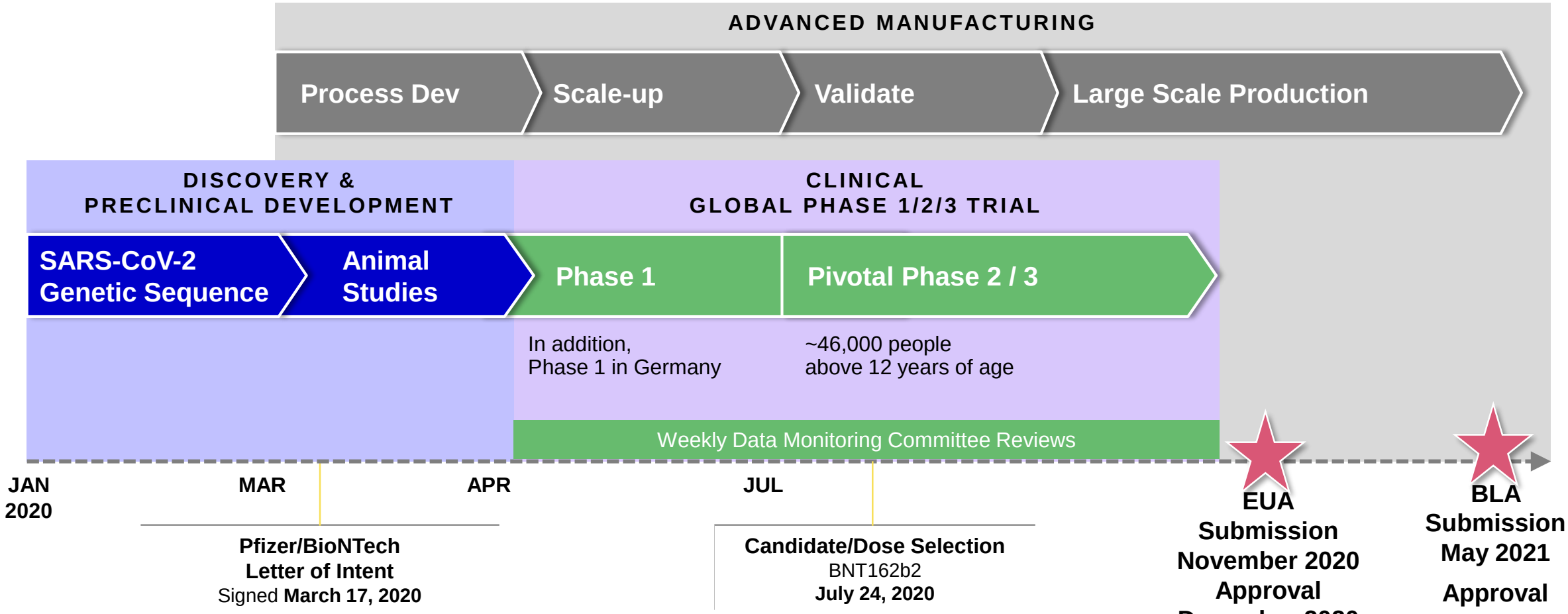
Selection of Pfizer/BioNTech COVID-19 vaccine BNT162b2



	Variant	Target	RNA Construct	Regimen
1	162a1	RBD subunit	uRNA	Prime/boost
2	162b1	RBD subunit	modRNA	Prime/boost
3	162b2	P2-mutated full spike protein	modRNA	Prime/boost
4	162c2	P2-mutated full spike protein	saRNA	Single injection

uRNA: unmodified mRNA
modRNA: nucleoside modified mRNA saRNA: self-amplifying mRNA
1. Wrapp et al., 2020, *Science.*

Responding to the Global Health Crisis with the BNT162b2 Vaccine



Note: All future dates represented in graphic reflect anticipated timelines and are subject to clinical, technical, and regulatory success

Looking Ahead: 2021, 2022 and Beyond

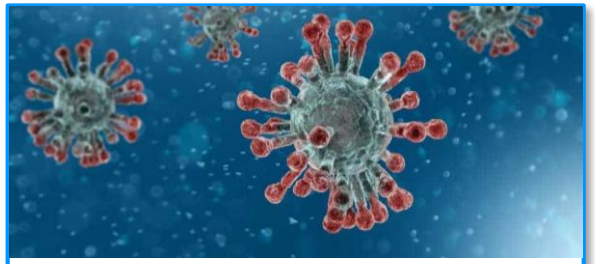
Potential Next Steps for BNT162b2

Ramp up production

Develop new dosage formulation

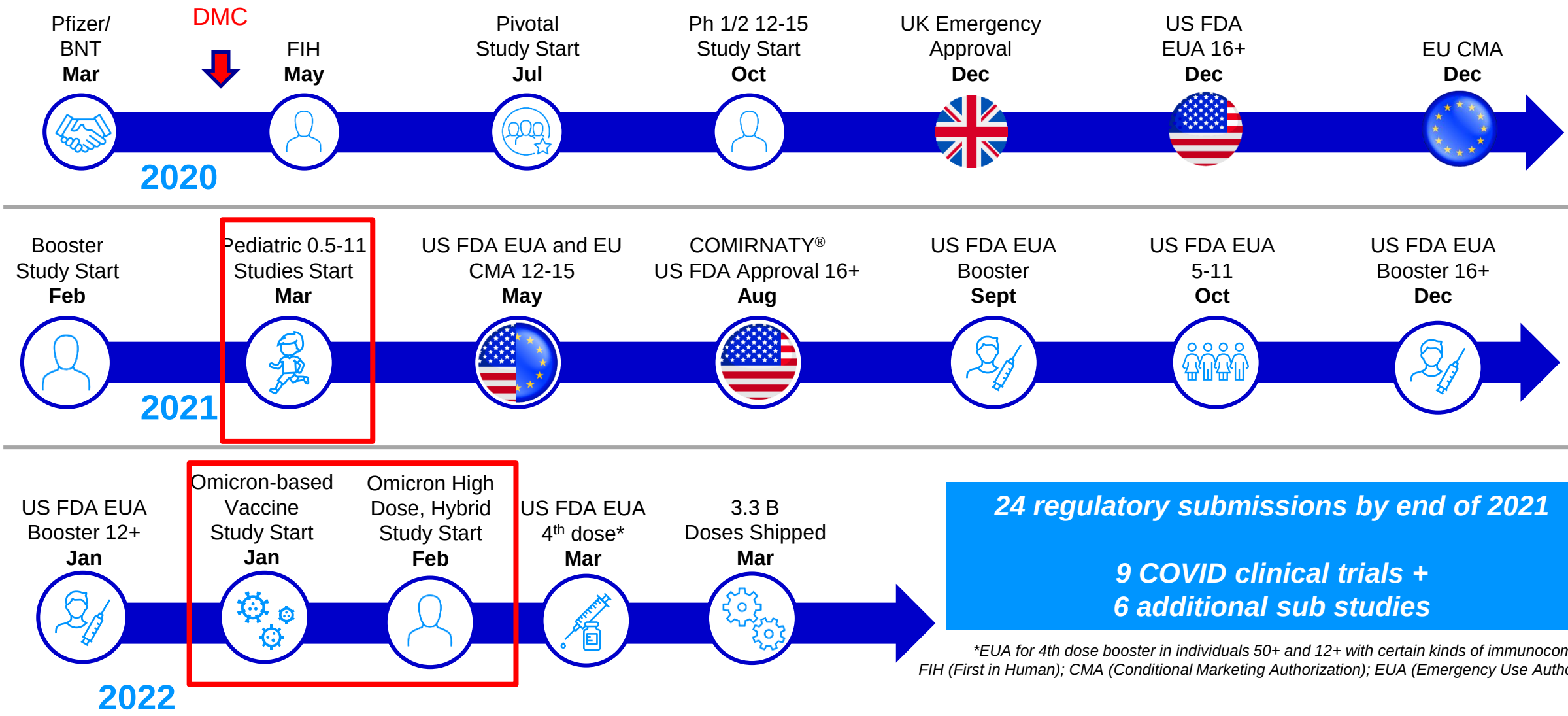
Explore boost for durability and optimal variant protection

Extend use in additional populations



Prepare for emerging SARS-CoV2 strains

The remarkable journey of developing BNT162b2 is ongoing as we enter the 3rd year of the pandemic –



24 regulatory submissions by end of 2021

9 COVID clinical trials +
6 additional sub studies

**EUA for 4th dose booster in individuals 50+ and 12+ with certain kinds of immunocompromise*
FIH (First in Human); CMA (Conditional Marketing Authorization); EUA (Emergency Use Authorization)

Pfizer-BioNTech Pediatric COVID-19 Vaccine BNT162b2: Study Overview: 5 to <12 Years

Phase 1

48
PARTICIPANTS

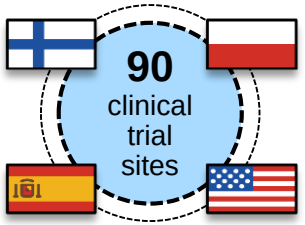
5 to <12 yrs

Identification of preferred dose level(s)

10 µg	20 µg	30 µg

Phase 2/3

2:1
randomization



~1500 BNT162b2

750 placebo

~Additional 1500 BNT162b2 and 750 placebo recipients most with ≥2 weeks post dose 2 safety data

Non-inferior immune responses have been established to infer vaccine efficacy

Children 5 to <12 years of age	Compared to	16–25-year-olds from the pivotal Phase 3 study

Although not required for EUA approval, COVID-19 surveillance was conducted permitting evaluation of vaccine efficacy

Immunobridging Criteria Between 5 to <12 and 16-25 Years of Age Were Met Both for GMR and for Seroresponse

Assay	Dosing/Sampling Time Point	BNT162b2 (10µg) 5 to <12 Years n	BNT162b2 (10µg) 5 to <12 Years GMT (95% CI)	BNT162b2 (30µg) 16-25 years n	BNT162b2 (30µg) 16-25 years GMT (95% CI)	5 to <12 / 16-25 years GMR (95% CI)	5 to <12 / 16-25 years Met Immuno-bridging (Y/N)
SARS-CoV-2 neutralization assay - NT50 (titer)	2 / 1 Month	264	1197.6 (1106.1, 1296.6)	253	1146.5 (1045.5, 1257.2)	1.04 (0.93, 1.18)	Y

Immunobridging is declared if the lower bound of the 95% confidence interval of the GMR is > 0.67 and the GMR is ≥0.8

Assay	Dosing/Sampling Time Point	BNT162b2 (10µg) 5 to <12 Years N	BNT162b2 (10µg) 5 to <12 Years n (%) (95% CI)	BNT162b2 (30µg) 16-25 years N	BNT162b2 (30µg) 16-25 years n (%) (95% CI)	Difference in % 5 to <12 / 16-25 years % (95% CI)	Difference in % 5 to <12 / 16-25 years Met Immuno-bridging (Y/N)
SARS-CoV-2 neutralization assay - NT50 (titer)	2 / 1 Month	264	262 (99.2) (97.3, 99.9)	253	251 (99.2) (97.2, 99.9)	0.0 (-2.0, 2.2)	Y

Seroresponse defined as achieving a ≥4 fold rise from baseline (before Dose 1)
Immunobridging is declared if the lower bound of the 95% confidence interval for the percentage difference is greater than -10

High Efficacy was Observed in 5 to <12 Year Olds Descriptive Analysis of First COVID-19 Occurrence From 7 Days After Dose 2

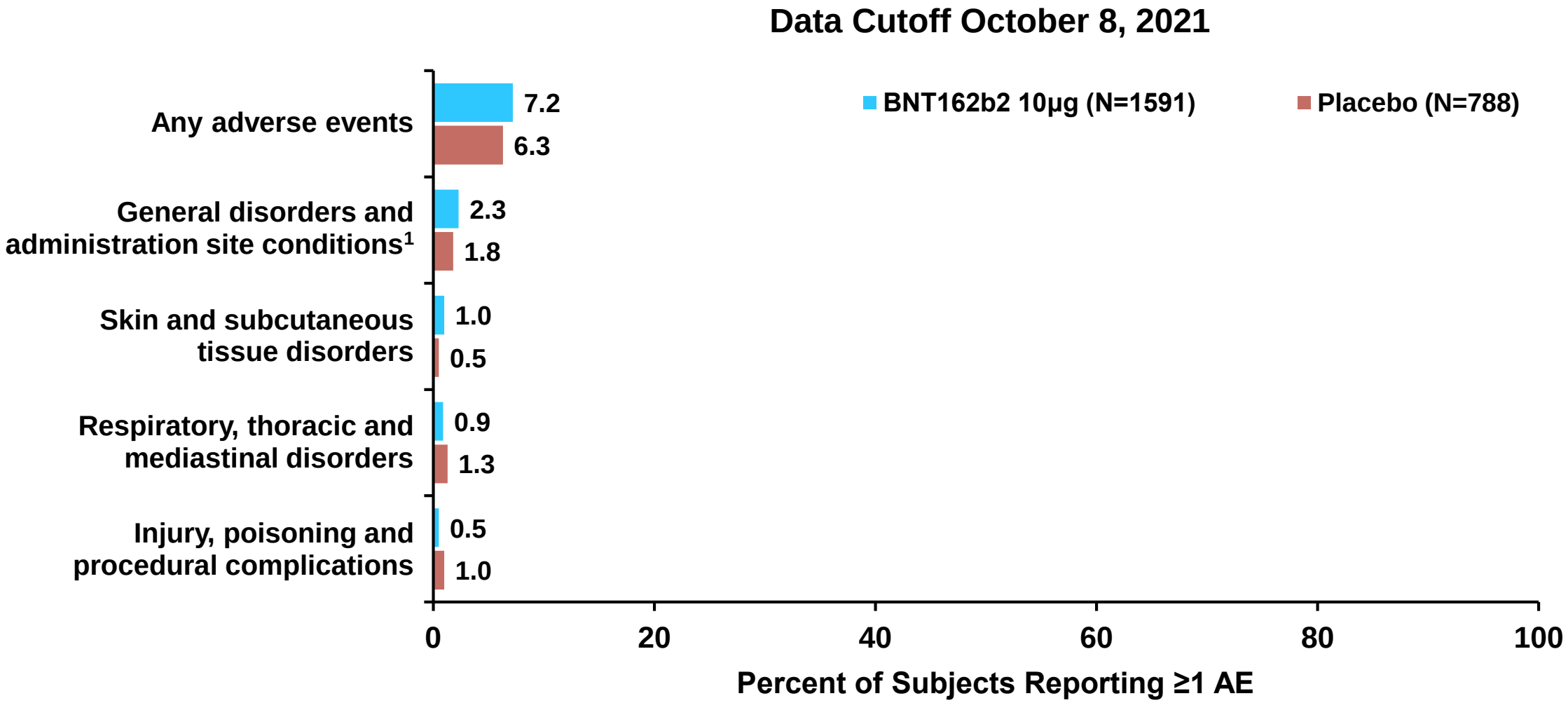
Subjects WITHOUT Evidence of Infection Prior to 7 Days After Dose 2

	BNT162b2 (10 µg) N=1305		Placebo N=663			
Efficacy Endpoint	**n**	**Surveillance Time (n)**	**n**	**Surveillance Time (n)**	**VE (%)**	**(95% CI)**
First COVID-19 occurrence ≥7 days after Dose 2	**3**	**0.322 (1273)**	**16**	**0.159 (637)**	**90.7**	**(67.7, 98.3)**

No severe cases of COVID-19 were reported
No cases of MIS-C were reported

Total surveillance time: 1000 person-years for all subjects within each group at risk for the endpoint

Adverse Events ≥1.0% by System Organ Class for 5 to <12 Year Olds from Dose 1 to Cutoff Date Safety Expansion Group (N= 2379)



1. Predominantly reflect local reactions at the injection site and systemic reactions of fatigue Lymphadenopathy 0.4% in the BNT162b2 group

The NEW ENGLAND JOURNAL of MEDICINE

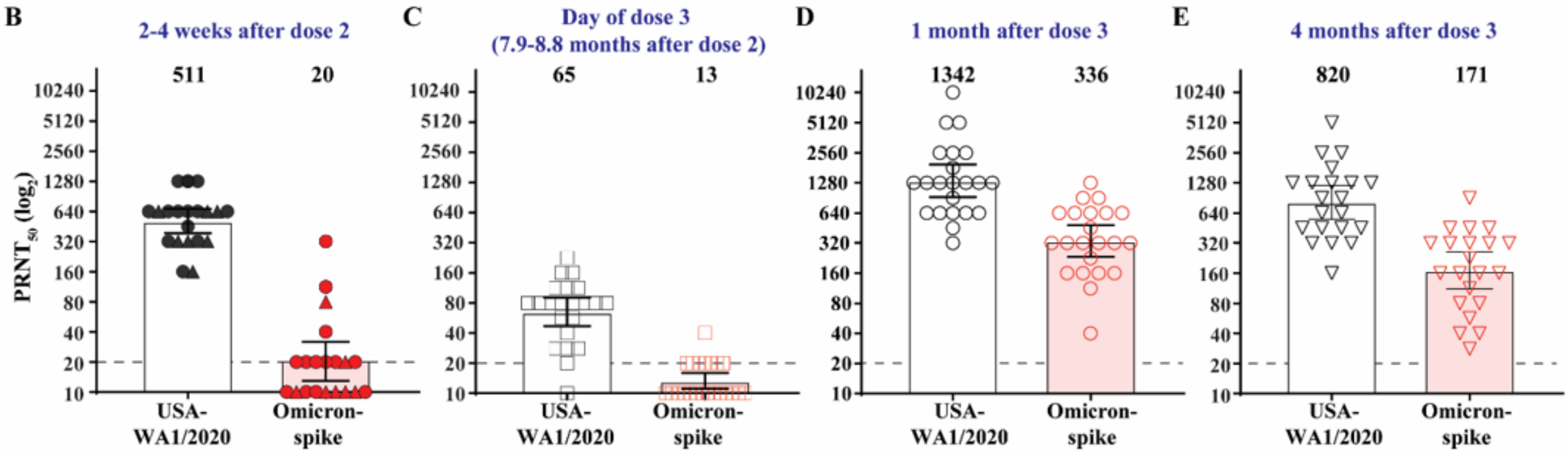
ORIGINAL ARTICLE

Evaluation of the BNT162b2 Covid-19 Vaccine in Children 5 to 11 Years of Age

E.B. Walter, K.R. Talaat, C. Sabharwal, A. Gurtman, S. Lockhart, G.C. Paulsen, E.D. Barnett, F.M. Muñoz, Y. Maldonado, B.A. Pahud, J.B. Domachowske, E.A.F. Simões, U.N. Sarwar, N. Kitchin, L. Cunliffe, P. Rojo, E. Kuchar, M. Rämet, I. Munjal, J.L. Perez, R.W. Frenck, Jr., E. Lagkadinou, K.A. Swanson, H. Ma, X. Xu, K. Koury, S. Mather, T.J. Belanger, D. Cooper, Ö. Türeci, P.R. Dormitzer, U. Şahin, K.U. Jansen, and W.C. Gruber, for the C4591007 Clinical Trial Group*

This article was published on November 9, 2021, at NEJM.org.

Effective neutralization of SARS-CoV-2 Omicron with three doses of BNT162b2

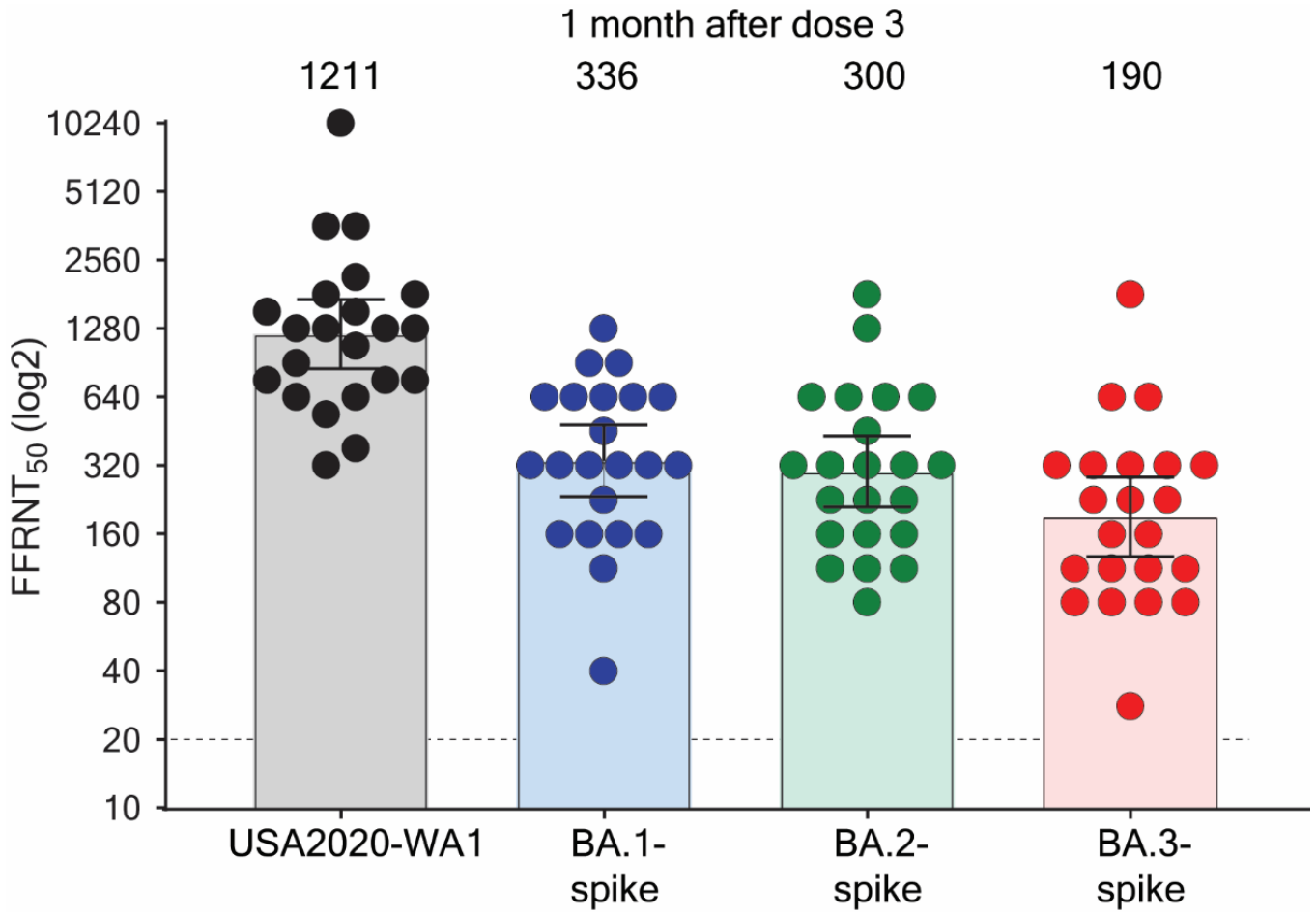


Recombinant SARS-CoV-2 with variant spike coding sequences on a common, USA-WA1/2020 genetic background
Circles: 2 weeks PD2. Triangles: 4 weeks PD2

BIONTECH

bioRxiv preprint doi: https://doi.org/10.1101/2022.01.21.476344

Similar neutralization activity against BA.1 and BA.2 with three doses of BNT162b2



Dose 3 administered 7 to 9 months after Dose 2

bioRxiv preprint doi: https://doi.org/10.1101/2022.03.24.485633

COVID-19 Clinical trial Evaluation of High Dose, Omicron, Bivalent

C4591031	To Evaluate the Safety, Tolerability, Efficacy and Immunogenicity of BNT162b2 Boosting Strategies Against COVID-19 in Participants ≥12 Years of Age. - Full Text View - ClinicalTrials.gov A PHASE 3 MASTER PROTOCOL TO EVALUATE ADDITIONAL DOSE(S) OF BNT162B2 IN HEALTHY INDIVIDUALS PREVIOUSLY VACCINATED WITH BNT162B2	BNT162b2	Substudy A Safety and efficacy ≥16 years of age Placebo-controlled, booster dose 30 µg
		BNT162b2	Substudy B Troponin response in ≥12 and ≤30 years of age Placebo-controlled, booster dose 30 µg
		BNT162b2	Substudy C Participants ≥12 years of age Booster dose 10 or 30 µg
		BNT162b2 BNT162b2 (OMI)	Substudy D Safety and immunogenicity in participants 18 to 55 years of age Cohort 1: as booster dose 30 µg Cohort 2: as second booster dose 30 µg (small group 2 doses at one month interval) Cohort 3: 2 doses in unvaccinated participants
		BNT162b2 BNT162b2 (OMI) Bivalent	Substudy E Safety and immunogenicity of second booster in participants ≥55 years of age Doses 30 µg, 60 µg
		BNT162b2 BNT162b2 (OMI) Bivalent	Substudy F Safety and immunogenicity of second booster in participants ≥60 years of age Doses 30 µg, 60 µg

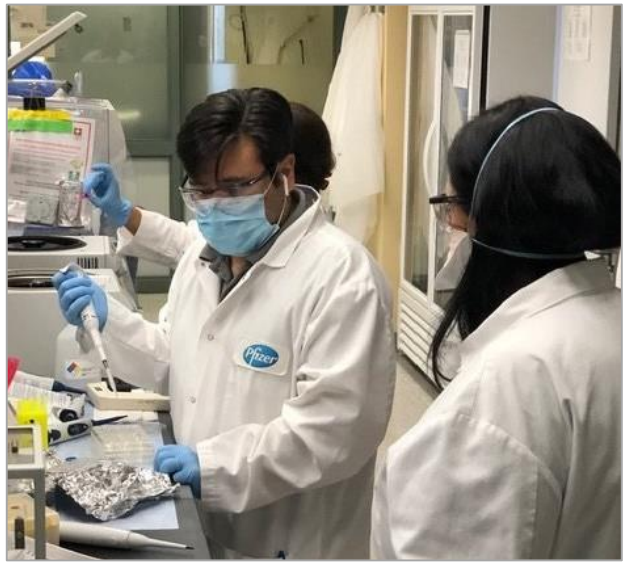
https://clinicaltrials.gov/ct2/show/NCT04955626 accessed April 20, 2022

Pfizer and BioNTech wish to thank:

- The clinical trial participants and their families
- Sites, investigators and their dedicated staff
- Our clinical trial CRO and other partners
- Governments and Regulatory Authorities
- Operation Warp Speed for knowledge exchange
- Colleagues at BioNTech, and Pfizer
- DMC







Thank you!

What/Who are DMCs (also called DSMBs and how do they work

- DMCs are considered to have “stewardship” of the trial. The Board has responsibilities to monitor safety and efficacy, and to ensure the validity of results
- Board members are **independent,** are paid hourly consultants and are extensively vetted for conflicts of interest
- Unblinded data are “Firewalled” from the study team(s)

Refernce on DMCs:
Susan Ellenberg, Thomas Fleming, David DeMets, Data Monitoring Committees in Clinical Trials
A Practical Perspective (John Wiley & Sons Inc., 2002) ISBN 0-471-48986-7

Membership

- Should reflect the disciplines and specialties necessary to interpret the data and evaluate participant safety.
- The number of DMC members depends on the phase of the trial, range of medical issues, complexity of design and analysis, and potential level of risk.
- Generally, consists of three to seven members including;
  - Clinical experts on disease and population studied
  - One or more biostatisticians
  - Investigators with expertise in clinical trial conduct and methodology
  - Bioethicist may also be included

What do we look at?

- Data quality, completeness, and timeliness
- Performance of individual centers
- Adequacy of compliance with goals for recruitment and retention, including those related to the participation of women and minorities
- Adherence to the protocol
- Interim/cumulative data for evidence of study-related adverse events
- Interim/cumulative data for evidence of efficacy according to pre-established guidelines
- Factors that might affect the study outcome or compromise the confidentiality of the trial data (such as protocol violations, unmasking, etc.)
- Factors external to the study such as scientific or therapeutic developments that may impact participant safety or the ethics of the study.

DMC Meetings have Open (Blinded) and Closed (Unblinded) Sessions

Minutes of both are part of FDA submission package

OPEN Session (Full Project Team)

- Protocol changes
- Screening, Accrual and Follow up rates
- Demographics
- Adverse events
- Accrual of Protocol Defined events

CLOSED Session (DMC Only)

- Adverse events by randomization group (active/placebo)
- Reactogenicity assessments
- Lab data analysis
- Severe adverse event narrative reports
- Scheduled Interim Analyses

The Charter

This Pre-specified document defines the role and operations of DMC

- “After each meeting, the committee will provide one of the following recommendations to Pfizer…
  - ***Withhold final recommendation until further information/data is provided***
  - ***Continue the study or studies as designed***
  - ***Modify the study or studies and continue*** *[(e.g increase sample size]*
  - ***Stop the study or studies***”….

    (can occur for safety or after interim analyses: efficacy or futility)

  DSMB may also advise on study site performance, recommend additional analyses or corrective actions

Key FDA Guidance for Vaccine EUAs -2020
--the roadmap--

- **Efficacy Guidance :**

…"the primary efficacy endpoint … should be at least 50%" -with lower bound of the confidence interval of 30%

- **Safety in Phase 3 Guidance**

"Data from phase 3 studies should include a median follow-up duration of at least 2 months after completion of the full vaccination regimen to help provide adequate information to assess a vaccine's benefit-risk profile. "

(These data were imputed the second week of November 2020)

Unique Challenges for the Pfizer DMC

- Rapid Phase 1 studies followed immediately by parallel Phase 2 studies
- Unprecedented study enrollment pace (1000s enrolled/week) in 134 sites
- Overwhelming amount of data
- New Vaccine Technology (mRNA)
- Previous reports of concerns about Vaccine-enhanced disease
- High Profile and High Impact
- Need to do everything remote

How did we respond

- Weekly DMC meetings from July 2020-December 2020 with data review packets sent earlier for review
- Additional “official” and “unofficial” ad hoc meetings to discuss issues, strategic DMC planning
- Continual communication with sponsor for additional analyses and clarifications with rapid turnaround

Examples of DMC interactions with Sponsor
This was an “Active” or “Dynamic” DMC

- Four sets of formal questions before Nov 2020
- DMC Request for additional analyses on appendicitis and lymphadenopathy adverse events due to initial imbalance–including recoding of some cases and pathology requests (based on data review and SAE narratives)
- Multiple analyses on reactogenicity (especially in kids)
- Recoding (“Bundling”) of atherosclerotic and thrombotic vascular events (e.g MI, angina, ischemia etc) to assess trendlines with greater power
- Emergent DMC Meeting to assess thrombotic events and thrombocytopenia after this was seen in the adenovirus vector vaccines (no similar safety concerns seen in this study)
- Multiple inquiries on statistical plan and study design issues
- DMC strongly advised against unblinding subjects in case of SAEs
- This continued—for example after approval-- DMC was aggressive about requesting information and access to SAE reviews on chest pain.

Dilemma in Fall 2020

- The FDA EUA Guidance requires 2 months follow up on 50% of subjects—for safety. In this case, it is 22,000 subjects followed for 2 months (total 44,000)
- Protocol defined cases (symptomatic COVID) accruing rapidly
- Safety endpoint will not be reached until November 10
- What happens if an interim analysis efficacy endpoint is reached before safety assessment is complete—in the middle of a presidential election?
- Decision—Follow the roadmap! (Continue as designed until safety data endpoint reached)

Pre-specified interim analyses

Table 6 illustrates the boundary for efficacy and futility if, for example, IAs are performed after accrual of 32, 62, 92, and 120 cases in participants without evidence of infection before vaccination. Note that although the first IA was not performed, the statistical criterion for demonstrating success (posterior probability threshold) at the interim (>0.995) and final (>0.986) analyses remains unchanged. Similarly, the futility boundaries are not changed.

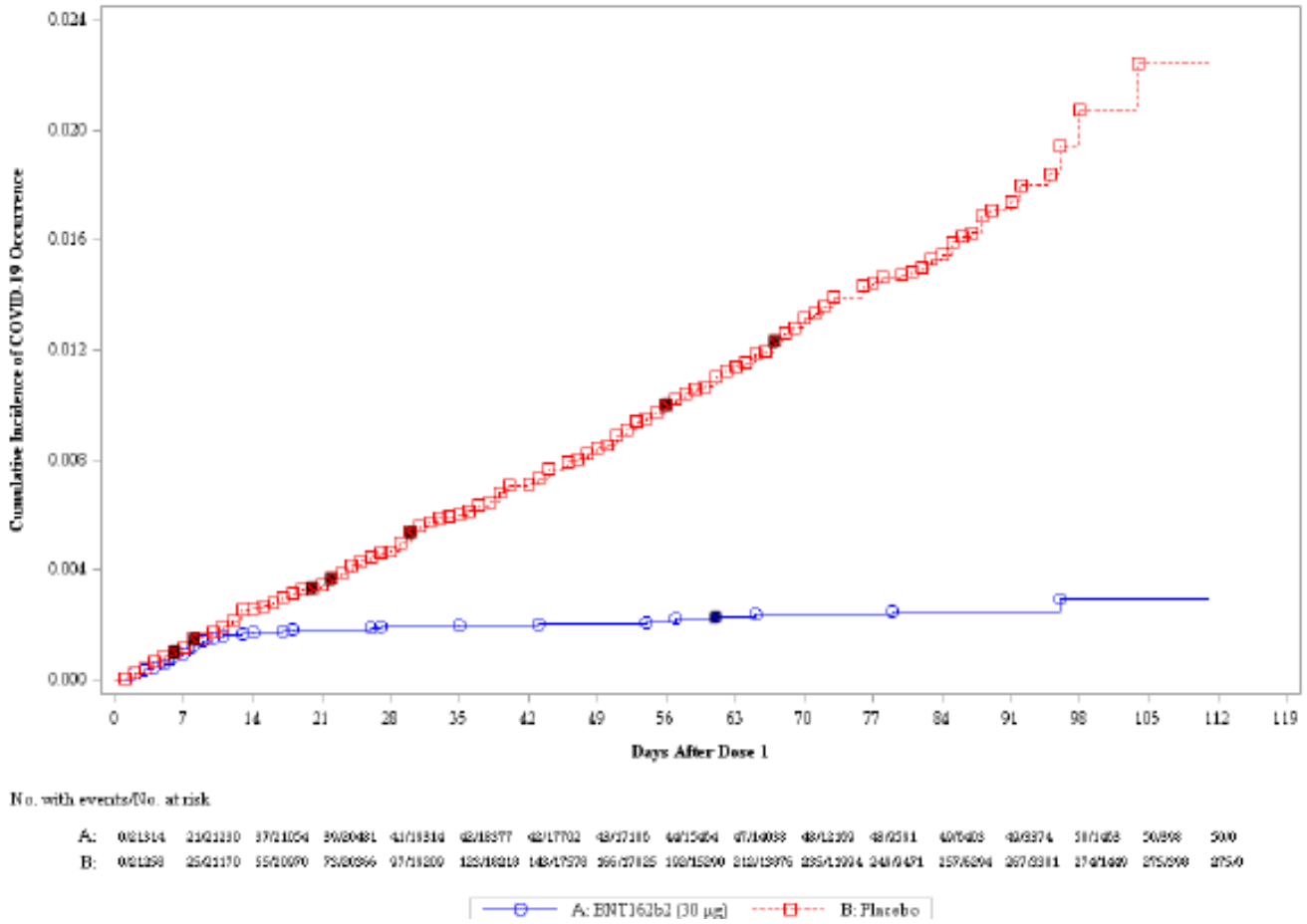
Table 6. Interim Analysis Plan and Boundaries for Efficacy and Futility

Analysis	Number of Cases	Success Criteria[a]	Futility Boundary
		VE Point Estimate (Case Split)	VE Point Estimate (Case Split)
IA1	32	76.9% (6:26)	11.8% (15:17)
IA2	62	68.1% (15:47)	27.8% (26:36)
IA3	92	62.7% (25:67)	38.6% (35:57)
IA4	120	58.8% (35:85)	N/A
Final	164	52.3% (53:111)	

Abbreviations: IA = interim analysis; N/A = not applicable; VE = vaccine efficacy.
Note: Case split = vaccine : placebo.
a. Interim efficacy claim: P(VE >30%|data) > 0.995; success at the final analysis: P(VE >30%|data) > 0.986.

The interim analysis split on November 8 2020 was
4:91
VE 95.5%
(88.4-98.4%)

Figure 13 Cumulative Incidence Curves for the First COVID-19 Occurrence After Dose 1 – Dose 1 All-Available Efficacy Population



Graphic Source: Pfizer Submission to FDA Dec 10, 2020

DMC Role since Nov 2020

- Recommended crossover immunization of placebo recipients asap
- Monthly meetings at least with continued data safety review of ALL studies detailed by Dr Gruber including the original study which goes for 2 years
  - Safety of boosters
  - Safety of variant boosters/ variant combos
  - Pregnant women
  - Children (5-11; 6mo-5 years)
- Continued discourse on dose and dosing schedule , analysis plans and future studies including epidemiological assessments and serology analyses

The New York Times | https://www.nytimes.com/2022/02/11/us/politics/fda-children-pfizer-vaccine.html

In Reversal, F.D.A. Delays Push for Shots for Children Under 5

The agency will wait for data on whether three doses of Pfizer-BioNTech's Covid vaccine are effective in young children after new, disappointing data.


- It was known that the non inferiority immunobridging endpoint was met for the 6-24 month old group but not for the 2-5 years old [3 ug dose]
- **The DMC found no safety issue**, and after review of the data recommended to proceed with a 3-shot series (including boost the eligible children already enrolled in the study) with anticipation to meet the endpoint later in the spring
- The press release in fact stated: *The independent data monitoring committee (DMC) for the study supports the continuation of the trial according to the protocol and support a potential 3-dose regimen*

https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-provide-update-ongoing-studies-covid-19
https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-provide-update-rolling-submission

Our Group

- Jonathan Zenilman –Johns Hopkins adult ID –chair
- Kathryn Edwards –Vanderbilt PEDS ID
- Robert Belshe –St Louis Univ—Adult ID
- Larry Stanberry –Columbia Univ –PEDS ID
- Steve Self- University of Washington –Biostat

- R Phillip Heine – Wake Forest Univ—OBGYN
- Heather Lipkind—Yale Univ--OBGYN

Summary

- Safety monitoring of the COVID vaccine trials has been one of the most intensive data oversight projects ever undertaken
- Pre-defined protocol data analysis procedures and interim analyses rules are invaluable and present a clear roadmap
- Constant communication between the sponsor and DMC is critical, while respecting firewall boundaries.

Session Outline

- By the end of this session, participants will be able to
  - Describe the development and implementation of the Pfizer COVID-19 vaccine program
  - Define the Role and Operations of Data Monitoring Committees (DMC)
  - Discuss how interim analyses contribute to safety in the Pfizer COVID-19 vaccine clinical trials

SLIDES & RECORDINGS
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Or search for “CCGHE COVID-19”